IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Paboojian et al. Application No: 09/731,318 Confirmation No: 1028 Filed: December 6, 2000 Title: RECEPTACLES TO FACILITATE THE EXTRACTION OF POWDERS	Group Art Unit: 3734 Examiner: Mendoza, Michael G. Attorney Docket No: 53246-US-CNT[2] (NV.0050.01) November 13, 2012 San Francisco, California

APPEAL BRIEF

VIA ELECTRONIC FILING

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner:

In response to the Examiner's Final Rejection of March 14, 2012, the Advisory Action of July 5, 2012 and the Notice of Appeal filed on July 13, 2012, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby appeals to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection. This Appeal Brief is accompanied by a request and fees for a two-month extension of time.

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By: /Libby Wilke/ Date: November 13, 2012
Libby Wilke

(1) *Real Party in Interest*

The real party in interest of the present application is Novartis AG (by way of assignment from Novartis Pharmaceuticals AG and from Nektar Therapeutics, which was formerly Inhale Therapeutic Systems, Inc.), having a place of business at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

(2) *Related Appeals and Interferences*

Appellant, Appellant's legal representative, and assignee are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

(3) *Status of Claims*

Claims 1-4, 13-22 and 31-34 are presently pending in the case. Claims 1-4 have been finally rejected. Claims 13-22 and 31-34 have been allowed. The rejection of each of claims 1-4 is hereby appealed.

Claims 5-12 and 23-30 have been cancelled.

(4) *Status of Amendments*

No claim amendments have been filed after Final Office Action. Accordingly, all claim amendments submitted during prosecution have been entered.

An After Final response was filed on June 14, 2012. The remarks were entered and considered by the Examiner as addressed in the Examiner's Advisory Action mailed on July 5, 2012. It is unclear whether or not the Examiner maintained the rejection under 35 U.S.C. §112, first paragraph. It is assumed for the purposes of this Brief the rejection was maintained.

(5) *Summary of the Claimed Subject Matter*

As recited in claim 1, a system is described for aerosolizing a powdered medicament. The system comprises a dry powder inhaler (see Figures 10, 12 and 15 and elements 90, 134, 200) and a receptacle (see element 10, Figures 1-4 and 7-15, and the discussion on pages 10-17). The receptacle (10) comprises a receptacle body (12) that defines a sealed cavity (20) containing powdered medicament, wherein the receptacle body has a top end (14) and a bottom end (16). The bottom end (16) of the receptacle body (12) includes a raised central region (26) that extends upwardly into the cavity (20, see page 9 lines 1-17 and page 10 line15 through page 11 line 12). The receptacle (10) is shaped and adapted to be insertable into the dry powder inhaler (90, 134, 200). The raised central region (26) is shaped to facilitate extraction of the powdered medicament when air or another gas is drawn through the cavity (20) so that the powdered medicament exits the cavity only through the top end (14).

(6) *Grounds of Rejection to be Reviewed on Appeal*

Appellant requests review of the Examiner's following grounds of rejection:

Claims 1-4 have been rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement.

Claims 1-4 have been rejected under 35 USC §103(a) as being unpatentable over EP 1106196 to Ohki et al (hereinafter Ohki et al).

(7) *Argument*

Appellant believes each of claims 1-4 are improperly rejected and are therefore allowable for the following reasons.

The rejections under §112, first paragraph are improper

The Examiner's rejection of claims 1-4 under 35 USC §112, first paragraph, as failing to comply with the written description requirement is improper and should be reversed.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *Moba, B.V. v. Diamond Automation, Inc.* 325 F.3d 1306, 1319 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar,* 935 F.2d at 1563.

An Applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.,* 107 F.3d 1565, 1572 (Fed. Cir. 1997). An Applicant may show possession of an invention by disclosure of drawings that are sufficiently detailed to show the Applicant was in possession of the claimed invention. *Vas-Cath,* at 1565. "[D]rawings alone may provide a 'written desription' of an invention." *In re Wolfensperger,* 302 F.2d 950. "In those instances where a visual representation can flesh out words, drawings may be used in the same manner and with the same limitations as the specification." *Eli Lilly*, 119F.3d at 1568.

Compliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis. *Vas-Cath,* at 1563.

In the present case, the Examiner has erroneously found that the addition of the term "only" in claim 1 in the amendment of December 22, 2011 constituted new matter and did not meet the written description requirement. According to the Examiner, "[t]here is no written description in the specification reciting that the powdered medicament exits the cavity **only** through the top end." (Page 2, Final Office Action, emphasis Examiner's). Applicant traverses this rejection.

That medicament exits the cavity only through its top end is described throughout Applicant's specification as originally filed. For example, consider the following recitation beginning on Page 3 at line 4 (emphasis added): "… an extraction tube is inserted into the cavity such that the bottom end is aligned with the raised central region and is spaced above the bottom end of the receptacle." The extraction tube is way medicament exits the cavity. Thus, if the bottom end of the extraction tube is inserted into the cavity and is spaced from the bottom end, it follows that medicament is only exiting through the top end. Specific recitation that the extraction tube is inserted into the top end is provided, for example, beginning on Page 3 at line 23: "…a hole is pierced through the top end of the receptacle to permit the extraction tube to be inserted into the cavity through the hole in the top end." From these recitations, it would be clear to one of ordinary skill in the art the medicament exits only through the top end. Numerous additional places throughout the specification make clear that the extraction occurs through the top end of the receptacle (for example see Page 10 lines 18-23).

In addition, the drawings provide clear support for the claim language. For example, Figure 4 and its associated discussion make clear that the extraction occurs only through the top end. Figure 4 itself tells a thousand words, as the saying goes, and among those words are that the medicament exits only through the top end. Explicit recitations like the one mentioned in the previous paragraph make clear what is meant by terms such as the top end.

After considering Figure 4 and the other relevant recitations in the specification, one of ordinary skill in the art would recognize that Applicant had possession of the

invention as claimed in claim 1 at the time of filing. Accordingly, claim 1 does not introduce new matter and properly meets the written description requirement of 35 U.S.C. §112, first paragraph. Appellant requests reversal of the rejection.

The rejections under §103(a) are improper

The Examiner's rejection of claims 1-4 under 35 U.S.C. §103(a) as being unpatentable over EP 1106196 to Ohki et al (hereinafter Ohki et al) is improper and should be reversed.

Ohki et al does not render independent claim 1 unpatentable. Claim 1 is to a system comprising, inter alia, a dry powder inhaler and a receptacle. The receptacle comprises, inter alia, a top end and a bottom end, wherein the bottom end of the receptacle body includes a raised central region that extends upwardly into the cavity, and wherein the raised central region is shaped to facilitate extraction of the powdered medicament when air or another gas is drawn through the cavity so that the powdered medicament exits the cavity only through the top end. Ohki et al does not disclose these features as claimed. For example, as shown in Figure 19, Ohki et al discloses powder outflow (H2) at both the top and the bottom of the blister. Since Ohki et al does not disclose each and every feature set forth in claim 1, it does render claim 1 unpatentable.

To make up for the deficiencies in Ohki et al in rendering claim 1 unpatentable, the Examiner goes on to posit that it would have been obvious to one of ordinary skill in the art to puncture only the top of the receptacle in Ohki et al (see Page 3 of Final Office Action). However, the Examiner provides no evidence, teaching or reasoning as to why this proposed modification would have been obvious to the person of ordinary skill. Accordingly, the Examiner has not satisfied the evidenciary burden of 35 USC 103(a) and has not established a prima facie case.

Contrary to the baseless assertion of the Examiner, one of ordinary skill in the art *would not* have found it obvious to make the Examiner's proposed modification of Ohki et al. Ohki et al discusses the advantages of the multi-hole arrangement throughout the specification. For example, note column 15's discussion of the creation of turbulent flow and the subsequent effective diffusion and micronization of the medicament in the receptacle. Because of these teachings, one of ordinary skill in the art would be taught away from making the Examiner's proposed modification.

In the Advisory Action of July 5, 2012, the Examiner makes a new but improper argument to support the obviousness conclusion. The Examiner states that omission of the bottom openings in Ohki et al would have been obvious "since it has been held that omission of an element and it (sic) function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art." Appellant disagrees that this holding bears any relevance to the present case, as will be explained.

The Examiner fails to state the authority which is being relied upon. Nonetheless, the Examiner's statement of the reputed holding is easily distinguished in the case of the instant rejection. The Examiner's proposed modification (i.e. the elimination of the bottom holes H1 and H2 in Figure 19) would not result in device where the remaining elements perform the same functions in the same way as before. With the Examiner's proposed modification, all flow in Ohki et al would go through top holes H1 and H2 in Figure 19. The resulting flow would not be the same as before the omission. Instead, the entire flow dynamics would be altered. As one of ordinary skill would recognize, there would be significantly less flow through the Ohki et al receptacle, particularly in the bottom region. Thus, this is not the case of a simple omission of an element and subsequent loss of its function.

Furthermore, Ohki et al teaches away from the Examiner's proposed modification. For example, Ohki et al discusses the importance of turbulent flow (column 15 lines 10-14). By making the Examiner's proposed modification and

removing the bottom openings of Ohki et al, the flow would become less turbulent. Figures 11 and 19 both show the turbulence that is caused by having openings in both the top and the bottom of Ohki et al. In contrast to the specific teachings of Ohki et al, by only having top openings, the flow becomes more like Appellant's flow which is laminar (see Appellant's specification Page 11 lines 4-12). In addition, by eliminating the bottom holes of Ohki et al the overall area of the inflow openings would be reduced. Thus, the constriction 26 of Ohki et al would not be as pronounced as when there is are two inflow openings which would result in reduced flow velocity through the constriction. Accordingly, the turbulence will again be reduced by the Examiner's proposed modification. Since Ohki et al teaches away from eliminating the bottom holes in Ohki et al, one of ordinary skill in the art would not have found it obvious to do so.

For at least these reasons, claim 1 is not properly rejectable under 35 U.S.C. §103(a) as being unpatentable over Ohki et al. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the teachings of Ohki et al could be modified, with a reasonable likelihood of success. There is no evidence to suggest that this is a situation where the ordinary artisan could have modified the teachings in a manner that would result in the invention of claim 1 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 1 is allowable over the reference cited.

Applicant requests withdrawal of the rejection of claim 1 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 2-4 which depend from claim 1 and are not rendered unpatentable by Ohki et al for at least the same reasons as claim 1.

Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: November 13, 2012

By: /Guy V. Tucker/
Guy V. Tucker
Reg. No. 45,302

Guy Tucker
Janah & Associates
650 Delancey Street, Suite 106
San Francisco, CA 94107
Phone: (415) 538-1555
Fax: (415) 538-8380

(8) Claims Appendix

1. A system for aerosolizing a powdered medicament, the system comprising:

a dry powder inhaler and a receptacle, the receptacle comprising:

a receptacle body that defines a sealed cavity containing powdered medicament, wherein the receptacle body has a top end and a bottom end, wherein the bottom end of the receptacle body includes a raised central region that extends upwardly into the cavity, and wherein the receptacle is shaped and adapted to be insertable into the dry powder inhaler and wherein the raised central region is shaped to facilitate extraction of the powdered medicament when air or another gas is drawn through the cavity so that the powdered medicament exits the cavity only through the top end.

2. A system as in claim 1, wherein the receptacle body further comprises at least one curved wall that in combination with the raised central region forms a generally semi-toroidal geometry in the cavity.

3. A system as in claim 1, wherein a portion of the bottom end is flat in geometry.

4. A system as in claim 1, wherein the receptacle body further includes a tab extending from the cavity.

(9) Evidence Appendix

none

(10) Related Proceedings Appendix

none